

**IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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**MEDTECH PRODUCTS INC.,**

**Plaintiff,**

**v.**

**RANIR, LLC and  
CVS PHARMACY, INC.**

**Defendant.**

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**Civil Action No. 07 CV 03302-UA-LMS**

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**MEDTECH PRODUCTS INC.,**

**Plaintiff,**

**v.**

**DENTEK ORAL CARE, INC.,**

**Defendant.**

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**ECF FILED**

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**MEDTECH PRODUCTS INC.,**

**Plaintiff,**

**v.**

**POWER PRODUCTS, INC.  
d/b/a SPLINTEK,**

**Defendant.**

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**PLAINTIFF MEDTECH PRODUCTS INC.'S  
REBUTTAL CLAIM CONSTRUCTION BRIEF**

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COMES NOW Plaintiff Medtech Products, Inc. (“Plaintiff”) and pursuant to this Court’s Discovery Plan and Scheduling Order entered on May 31, 2007, hereby submits its Rebuttal Claim Construction Brief in opposition to Defendant DenTek Oral Care Inc.’s (“DenTek”) Memorandum on Construction of Claim 17 of the ‘051 Patent (“DenTek’s Memo”).

### **I. INTRODUCTION**

In this action, Plaintiff asserts infringement of Claim 17 of U.S. Patent No. 6,830,051 (“the ‘051 Patent”) by DenTek. Claim 17 is directed to a method of manufacturing a dental protector that prevents bruxing, i.e. grinding, and clenching, i.e. closing tightly, of the teeth and the tooth damage that can result from these events.

Plaintiff and DenTek have exchanged proposed constructions of the terms in Claim 17. Plaintiff and DenTek have been able to agree on stipulated definitions for eight of the thirteen material terms at issue in this case. The stipulated definitions are set forth in § III *infra*. As to the remaining five terms, Plaintiff proposes definitions that are consistent with the plain, ordinary meaning of the terms and the intrinsic evidence whereas DenTek proposes a variety of limitations upon the terms that are not consistent with the ordinary and customary meaning of the terms and the intrinsic evidence.

DenTek ignores the ordinary and customary meanings of the terms at issue in a transparent attempt to construe the terms of the ‘051 Patent in a manner solely to support its defenses. DenTek’s interpretations would have this Court add “all” to a definition where no support for this term exists; import improper limitations from the preferred embodiments into the claim; misinterpret the Patent Examiner’s reasons for allowing the invention; and impute limitations from independent Claim 1 of the ‘051 Patent into independent Claim 17.

Furthermore, DenTek’s construction not only improperly restricts the scope of Claim 17, but also creates a “moving target” for one of the most significant terms in Claim 17. In

DenTek's Preliminary Proposed Claim Construction of Claim 17 of the '051 Patent, it defined this term as "having approximately 30% by weight vinyl acetate."

Having **at least 27.0%** by weight vinyl acetate but not more than 33.0% by weight vinyl acetate

*Id.* (attached as ***Exhibit E*** to Plaintiff's Claim Construction Brief) (emphasis added). This definition, in essence, construed the word "approximately" to mean  $\pm 3.0\%$ . The clear purpose of selecting this range is to place its appliance, which 34.3% by weight vinyl acetate, outside of the scope of Claim 17.

After apparently realizing that this position lacked any support, DenTek now proposes that the same term be defined as:

Having **at least 25.0%** by weight vinyl acetate but not more than 33.0% by weight vinyl acetate

(DenTek's Memo at p. 24). In support of this unbalanced range (i.e.  $-5.0\%$  or  $+3.0\%$ ), it cites exemplar resins referenced in the preferred embodiment section of the '051 Patent. DenTek, however, ignores the applicant's express disclaimer of any specific resin, including those cited as exemplars.

For the reasons set forth below, this Court should adopt Plaintiff's proposed construction of the terms in dispute and reject DenTek's construction that imposes unsupported and improper limitations on the terms.

## **II. THE CLAIMED METHOD**

The present suit involves Claim 17 of the '051 Patent, which is directed to a method of fabricating an interocclusal appliance for alleviation of adverse effects of bruxing and/or clenching events. With reference to Fig. 5 of the '051 Patent that depicts an ***exemplary*** embodiment of the device, the method comprises the steps of (a) molding an appliance base (reference numeral 12) from a resin having particular physical properties discussed below and

(b) molding over the base (reference numeral 12) an impression preform (reference numeral 14) having particular physical properties discussed in § III *infra*. The molding of the impression preform to the base provides a unitary bonding of the base and the impression preform to resist bruxing and clenching of the teeth.

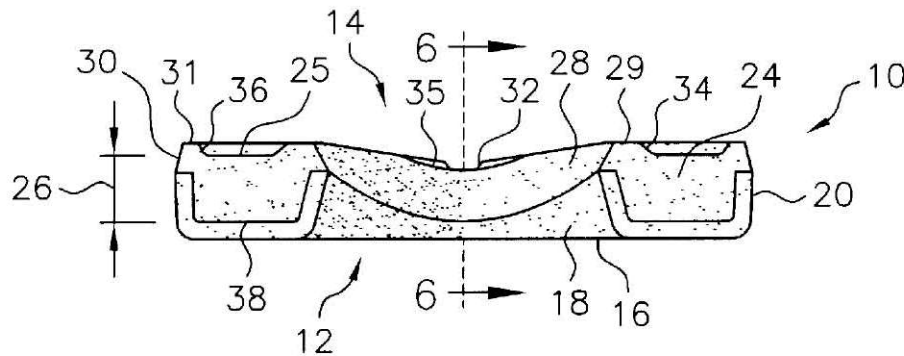


FIG. 5

### III. STIPULATIONS AND REMAINING TERMS TO BE CONSTRUED

### A. STIPULATED TERMS

The parties have stipulated to the definitions of the following terms:

1. ***molding and (sic) appliance base***: This phrase is to be construed as “molding an appliance base” and defined as “the step of forming or shaping the bottom support or layer of the appliance by molding.”
2. ***having a Vicat softening temperature***: This phrase is to be construed as “a temperature at which a flat-needle penetrates a specimen of the resin to the depth of 1 mm under a specific load when the resin is heated.”
3. ***of at least 70°C***: This phrase is to be construed as “a temperature of 70.0°C or more.”

4. ***a Shore A hardness***: This phrase is to be construed as “a measurement of the extent of indentation by the action of a Shore A durometer.”
5. ***of at least 80***: This phrase is to be construed as “a Shore A hardness of 80 or more.”
6. ***an ethylene vinyl acetate copolymer***: This phrase is to be construed as “copolymers of vinyl acetate and ethylene.”
7. ***bruxing***: This term is to be construed as “grinding of the teeth.”
8. ***clenching***: This term is to be construed as “clenching teeth tightly.”

**B. REMAINING TERMS TO BE CONSTRUED**

The definitions of the following terms remain in dispute and must be construed:

1. ***an interocclusal appliance***
2. ***a resin***
3. ***molding over the base***
4. ***an impression preform***
5. ***having approximately 30% by weight vinyl acetate***

**IV. PLAINTIFF’S CLAIM CONSTRUCTIONS**

**A. AN INTEROCCLUSAL APPLIANCE**

Plaintiff believes this term does not need to be defined as it is part of the preamble, and elements of the preamble generally are not restrictive claim elements, but provide context. However, to the extent necessary, this Court should adopt Plaintiff’s definition of the term as ***“an appliance that is used or fitted, in whole or in part, between portions of the upper and lower teeth.”*** DenTek’s definition of this term as ***“a device that prevents full occlusion of all teeth”*** should be rejected. That definition would require that an “interocclusal appliance”

prevent “full occlusion of **all teeth**.” As such, DenTek’s construction imposes limitations that are inconsistent with the plain, ordinary meaning of the term as supported by the intrinsic record.

The ordinary and customary construction of “interocclusal”, as used in relation to the type of appliance that is the subject of the ‘051 Patent, simply requires fitting **between** the teeth.<sup>1</sup> In contrast to DenTek’s construction, Plaintiff’s construction of “interocclusal” is consistent with both the intrinsic evidence of the specification and the file history. *Merriam-Webster’s Medical Dictionary* confirms that the ordinary and customary definition of “interocclusal” is “situated or occurring between the occlusal surfaces of opposing teeth.” See *Exhibit F* to Plaintiff’s Claim Construction Brief. *DentalGlossary.net* similarly defines the term as the “space between upper and lower teeth.” *Id.* There is nothing inherent in the term “interocclusal appliance” that supports a definition requiring “**full** occlusion of **all** teeth.” (emphasis added). In contrast, Plaintiff’s construction correctly describes the placement of the appliance as between the upper and lower teeth of the user.

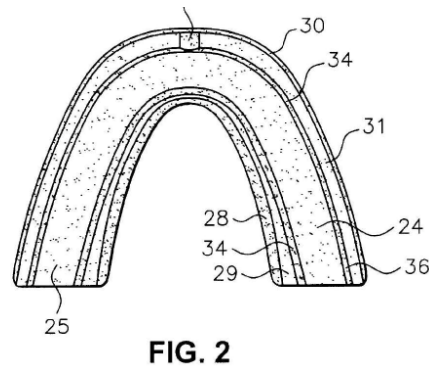
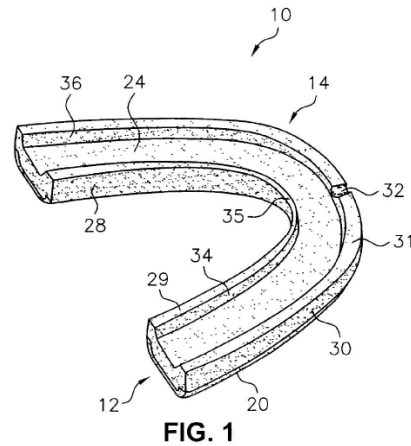
Plaintiff’s construction is consistent with the intrinsic evidence. The language of the other claims is replete with references to placing the appliance between the occlusal surfaces of the teeth. See Claims 12, 13, 15, and 16 of the ‘051 Patent. Moreover, the specification of the ‘051 Patent specifically references the placement of the invention. In the summary, it states that the device is to be molded against the maxillary arch of the user. See Col. 2, ll. 18-24.<sup>2</sup> It also is clear from Figs. 1 and 2 of the ‘051 Patent that the claimed invention is to be placed in the user’s mouth between the upper and lower teeth.

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<sup>1</sup> Plaintiff does not distinguish between the terms “appliance” and “device” in this context, and is willing to amend its definition to “**an appliance or device that is...**”

<sup>2</sup> All such references are to the column and lines numbers of the ‘051 Patent specification. See *Exhibit A* to Plaintiff’s Claim Construction Brief.





DenTek's construction seeks to add the word "all" before the word "teeth". There is no such limitation anywhere in the '051 Patent. Indeed, one of the stated objectives of the '051 Patent is to prevent "loss of *tooth* structure", not "not *all teeth* structure." See Col. 3, ll. 6-9; *accord*, Col. 3, ll. 13-17 ("...reduce ...forces upon individual tooth surfaces...").

Accordingly, the Court should either find that this term does not need to be defined, or should adopt Plaintiff's construction of this term as consistent with the specification and file history. DenTek's construction should be rejected because it imports extraneous limitations.

**B. A RESIN**

Plaintiff initially proposed that this term be defined as *“a moldable material”*. After consultation with DenTek’s counsel, Plaintiff now proposes that this Court should adopt a compromise definition of this term as *“one of a number of natural or synthetic substances and compounds that are solid or semi-solid after molding and may be thermoplastic or thermosetting.”* DenTek’s definition that a resin be defined as *“a synthetic organic compound consisting of a noncrystalline solid or viscous liquid substance”* should be rejected because it does not construe the term “resin” in a manner that is consistent with its ordinary and customary meaning and the intrinsic record.

Plaintiff’s definition is supported by the ordinary and customary meaning of the word. Although “resin” is not explicitly defined within the ‘051 Patent, the common and ordinary definition of “resin,” as confirmed by *The American Heritage College Dictionary*, is the following:

1. Any numerous clear to translucent yellow or brown, solid or semisolid viscous substances of plant origin, such as amber, used in lacquers, varnishes, inks, and plastics.
2. Any of numerous physically similar polymerized synthetics or chemically modified natural resins including thermoplastic material such as polyethylene and thermosetting materials such as polyesters that are used with stabilizers and other components to form plastics.

*Id.* at 1161. See **Exhibit H** attached to Plaintiff’s Claim Construction Brief.

Plaintiff’s definition also is supported by the intrinsic record. Indeed, the specification of the ‘051 Patent states, “It should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention.” Col. 10: 29-33. The references to synthetic resins in the exemplars in the ‘051 Patent do not limit the types of thermoplastic resins that are available for use with the invention.

Rather, the thermoplastic resins that may be used with the invention as claimed are limited only by the particular suitable softening temperature range and hardness of the base resin, as specified in Claim 17. *Id.* Accordingly, DenTek's construction should be rejected because it imposes limitations, particularly the limitation of "synthetic organic", that are inconsistent with the common and ordinary meaning and with the intrinsic record. Further, DenTek's construction creates a limitation by exclusion of natural resins, which are within the plain, ordinary meaning of the term resin.

Plaintiff's compromise definition incorporates the customary and ordinary meaning, the intrinsic record, and DenTek's request for more specificity. Plaintiff's previously proposed definition had included the phrase "organic or synthetic" but after reflection and consultation with DenTek's counsel, it became apparent that such a definition would incorporate limitations into Claim 17 that were not intended by the inventor.

Based upon the plain, ordinary meaning of this term, Plaintiff proposes the following compromise definition: ***"any of a number of natural or synthetic substances and compounds that are solid or semi-solid after molding and may be thermoplastic or thermosetting"***.

#### C. **MOLDING OVER THE BASE**

In defining ***"molding over the base"***, DenTek's construction attempts to draw support from the '051 Patent to require the resin to contact the "entire upper surface" of the base. However, the only support DenTek can cite improperly imports limitations from the specification and preferred embodiment. As such, this Court should adopt Plaintiff's definition of the term as ***"a step of molding over the base"*** and reject DenTek's definition as ***"contacting a heated resin with the entire upper surface of the appliance base."***

This term should be given its ordinary and customary meaning in the context of the intrinsic record. “Molding over the base” refers to the second step of fabricating an embodiment of the invention in which the impression preform is molded over the base to form the appliance. *See* Col 2, ll. 3-4; Col. 11, ll. 3-6; Col. 12, ll. 16-18. To the extent that the Court desires guidance as to the specific terms “molding” and “base”, it should refer the stipulated definition of ***molding an appliance base***, which is “the step of forming or shaping the bottom support or layer of the appliance by molding.”

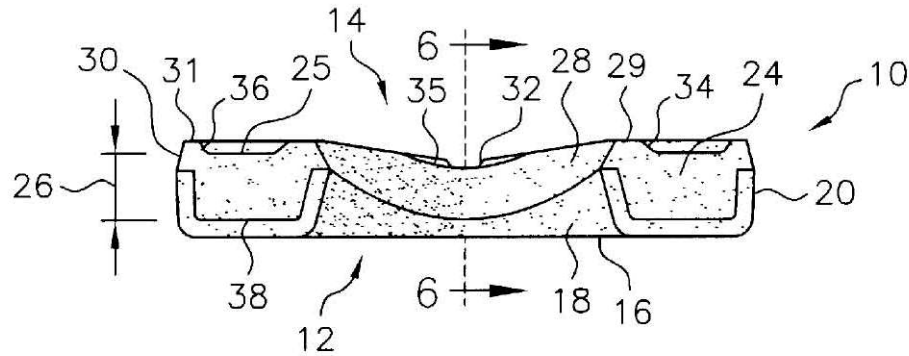
DenTek’s proposed definition imports limitations from the specification and preferred embodiment, including the exemplar embodiments, into the claim. *See* DenTek Memo, pp. 20-21. This is improper. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). “References to a preferred embodiment, such as those often present in a specification, are not claim limitations.” *Laitram Crop. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988).

Notwithstanding this improper importation of limitations, the portions of the specification cited by DenTek do not support its position. For example, DenTek cites the following language of the specification:

*The upper surface of the base and the opposed inner surfaces of the side walls 18, 20, all of which are bonded to the impression preform 14 when the preform is molded over the base, is designated by the reference numeral 38 in Fig. 5.*

Col. 4, ll. 46-50 (emphasis added). This description clearly and unequivocally states that the upper surface of the base and the *inner* surfaces of the side walls are bonded to the preform impression. It does not include the *top* of the side walls in the description of where the bonds are created. This is consistent with the later instruction that the surface identified as 38 in Fig. 5 may be coated or textured to promote bonding. Col. 10, ll. 39-51. Neither of these portions of the

'051 Patent's specification require that the entire surface, and for example the top of the side walls, must be contacted with the resin preform.



**FIG. 5**

DenTek's assertion that "over" means "so as to cover conceal or affect the whole surface or expanse" is not correct in view of certain aspects of the invention. The aspects relate to the bonding between the points of contact of the base and the impression preform, and do not mean that the entire upper surface of the appliance base would be covered. One of the aspects involves molding the impression preform over the base to accomplish a "high shear resistance bond" between the base and the preform. Col. 3, ll. 1-5. DenTek has not presented any argument or evidence to demonstrate that this strong bond requires that the entire base be covered or concealed. The language of the claim, and even the specification, make clear that there is no basis to allege that a preform molded over only a portion of the base surface would be insufficient to accomplish the creation of a "high shear resistance bond" between the contacting surfaces of the base and the impression preform.

Additionally, DenTek misinterprets the language of the Examiner's Reasons for Allowance where he refers to "impression material bonded to the base" and "the impression material has a pilot channel having a generally planar face and a pair of space (sic) peripheral

walls”. See Sieczk. Decl. at Ex. D, page 55. DenTek asserts that the “pair of spaced walls” could only be formed if the impression preform is molded over the entire walls of the base. This is structurally and factually incorrect. With reference to an exemplary embodiment shown in Fig. 5, the pilot channel 24 is formed in the upper surface of the impression preform 14. The pilot channel 24 has a recessed face 25 and peripheral side walls 28, 30. These spaced walls 28, 30 are defined by the recessed pilot channel in the top surface of the impression preform 14, and can be formed in the top surface whether or not the impression preform covers the entire width (as shown) or a narrower width portion of the base.

Further, the Examiner’s Reasons for Allowance makes no reference to whether the impression preform covers the entire base or even whether it covers the walls of the base. It simply refers to the pilot channel and pair of spaced walls. *Id.* There is no reason to infer as a matter of law that the Examiner’s Reason for Allowance really meant the entire the surface of the base. If the Examiner had intended such a limitation or interpretation, a statement to that effect would have been included in the Reasons for Allowance.

Moreover, an Examiner’s Statement of Reasons for Allowance “will not necessarily limit a claim.” *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345 (Fed. Cir. 2005). This is especially true where, as in the present case, the examiner’s unilateral statements are not contested by the applicant and the applicant has disavowed nothing. *See id.*

Plaintiff’s definition is correct. However, in order to expedite the Court’s interpretation, Plaintiff proposes the following compromise definition: ***“the step of forming the impression preform of the appliance into a shape on top of the appliance base.”*** DenTek’s limitation would improperly impose a requirement that the impression preform cover the entire surface of the base. This unsupported limitation should be rejected.

**D. AN IMPRESSION PREFORM**

This Court should adopt Plaintiff's definition of this term as *"a formable material overlying the base"* and reject DenTek's definition of this term as *"a hardened resin structure containing a channel with curving sides and a flat bottom, and a footing that extends from a horizontal upper surface of the base to the channel face."*

This term should be given its ordinary and customary meaning. Claim 17 defines the necessary process to fabricate the claimed dental protector. At its most basic level, the dental protector includes a formable material that captures the unique structure of the user's teeth and bonds to a base, to prevent bruxing or clenching. *See* Col. 2, ll. 3-4, 14-24; Col. 3, ll. 1-3.

DenTek's construction, however, seeks to import the limitations of Claim 1 into Claim 17. This is improper. The fact that specific structural elements were used in Claim 1 and not in Claim 17, in fact, demonstrates that the two claims have different scopes. Claim 17 is a stand-alone, independent claim. It is not a dependent claim. If the applicant had intended to limit the scope of Claim 17 to the specific structure recited in Claim 1, it would have included that language, as it did in independent Claims 1 and 13.

DenTek also seeks to import limitations from the preferred embodiment into Claim 17. This is improper. *See Innova/Pure Water*, 381 F.3d at 1117. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." *Laitram Corp.*, 863 F.2d at 865.

DenTek's reliance on *Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373 (Fed. Cir. 2002), for its contention that the Examiner's Reasons For Allowance supports its claim construction as a matter of law is misplaced. The Court in *Inverness* considered whether an examiner's argument in a rejection of a claim limited the use of the words "on" and "onto" in the claim. *Id.* at 1380-81. The Court held that the claim was not limited because when the

examiner invited the patentee to provide evidence that the prior art recognized the different techniques for a glazing method, the patentee provided such by amendment to the claims. In the present case, the examiner has provided a statement of reasons for allowance quoting structural elements of allowed Claim 1 but these structural elements not present in the method Claim 17 at issue. DenTek improperly attempts to bootstrap limitations from Claim 1 into Claim 17. Similarly, *Koepnick Med. & Educ. Research Found v. Alcon Labs*, 162 Fed. Appx. 967 (Fed. Cir. 2005) cited by DenTek considered construction of a term in the claim at issue in view of the intrinsic evidence, and not wholesale importation of limitations from one claim into another. As noted above, an Examiner's Reasons for Allowance will not necessarily limit a claim. *See Salazar*, 414 F.3d at 1345.

Further, DenTek contends in its Memo that "[t]he pair of spaced walls is formed only because the impression preform completely covers the base..." *Id.* at p. 21 (emphasis added). As discussed above, this contention is structurally and factually incorrect. The pair of spaced walls are formed by the pilot channel having a recessed face 24 and opposing side walls 28, 30, in the upper surface of the impression preform. *See* Fig. 5. Forming that structure in the upper surface is independent of whether the impression preform is completely covering the width of the base or has a width narrower than the base. DenTek also contends that the "entire surface of the base is bonded to the impression preform to provide a strong unitary bond". *Id.* at p. 21. That argument compares "apples to oranges". The requirement for strong unitary bond relates to the bonding between the surfaces that are in contact and does not relate to whether the area of the base is completely covered by a contacting surface of the impression preform or a portion of the area is covered.



Accordingly, this Court should adopt Plaintiff's definition of this term as *"a formable material overlying the base"* and reject DenTek's definition of this term.

**E. HAVING APPROXIMATELY 30% BY WEIGHT VINYL ACETATE**

DenTek's Memorandum presents a definition for this term that differs from the definition in DenTek's Preliminary Proposed Construction of Claim 17 of the '051 Patent, attached as Exhibit E to Plaintiff's Claim Construction Brief, in which DenTek defines this term as *"having at least 27.0% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate."* After apparently realizing that it had absolutely no basis for placing a limitation of +/-3% on the term, it now proposes a definition of *"having at least 25% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate"* – thereby changing the definition of "approximately" from +/-3% to -5% or +3%, without any explanation. Under this new definition, DenTek has abandoned a "balanced" range and instead, proposes an "unbalanced" range that conveniently places its infringing product, which contains an impression preform comprising an ethylene vinyl acetate copolymer having 34.3% by weight vinyl acetate, outside of the proposed range.

DenTek apparently relies upon the *exemplar* resins referenced in the preferred embodiment section of the '051 Patent. This reliance is misplaced. Plaintiff acknowledges that it referenced an EVA copolymer having a vinyl acetate content of at least 25% and a preferred EVA copolymer having a 33% vinyl acetate content by weight as *exemplar* resins for the impression preform. Col. 5, ll. 13-18. Plaintiff, however, specifically disclaimed any limitation imposed by these exemplars where it stated, "It should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention." Col. 10, ll. 29-32. Therefore, the references to the exemplars should not serve to "book end" the appropriate of range of weight of vinyl acetate.

DenTek's assertion that Claim 17 will fail the notice function of a patent if "approximately" is not precisely defined is misguided. Courts have consistently permitted the use of terms of approximation in claims. *See e.g. Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1582 (Fed. Cir. 1995) (interpreting "approximately" to mean "reasonably close to"); *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1455 (Fed. Cir. 1988) (finding reasonable likelihood of success on infringement claim containing the words "at least").

The word "approximately" has the commonly understood definition of "about, close to, just about, some, roughly, more or less, around, or so." *See Exhibit N* to Plaintiff's Claim Construction Brief. As the parties do not dispute the phrase "by weight vinyl acetate," Plaintiff proposes the following compromise definition: ***"having about, roughly, or around 30% by weight vinyl acetate."*** It then will be up to the finder of fact to determine whether a particular measurement of the impression preform layer of DenTek's appliance is about, roughly or around 30% by weight vinyl acetate.

Accordingly, the Court should adopt Plaintiff's proposed construction that "having approximately 30% by weight vinyl acetate" means "having about, roughly, or around 30% by weight vinyl acetate."

## **V. CONCLUSION**

For all of the foregoing reasons, Medtech respectfully requests its constructions of the above terms be adopted by the Court and DenTek's construction of the above terms be denied.

Dated: July 20, 2007.

Respectfully submitted,

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